



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,566	04/07/2006	Laura M'Rabet	0470-052056	2004
28289 7590 08/15/2007 THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			EXAMINER KOSSON, ROSANNE	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 08/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,566

Applicant(s)

M'RADET ET AL.

Examiner

Rosanne Kosson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-44 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1652

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse of Group II, claims 31-40, in the reply filed on July 23, 2007 is acknowledged. Claims 21-30 (Group I) are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. No claims have been amended or canceled. Claims 41-44 have been added. Accordingly, claims 31-44 are examined on the merits herewith.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 recites the limitation "beta-lactoglobulin" and a particular ratio of lactoferrin to beta-lactoglobulin. There is insufficient antecedent basis for this limitation in the claim, as claim 31 does not recite beta-lactoglobulin. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1652

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (US 6,887,850 B2) in view of Laiterie Cooperative de Baignes Sainte-Radegonde et ses Environs (FR 2296428 A1) (Sainte-Radegonde); Zehner et al. (US 6,777,397); Lands ("Biochemistry and physiology of n-3 fatty acids," FASEB Journal, 6:2530-2536, 1992; Cavazza (US 6,932,999) and Baylor College of Medicine (EP 295009 A2) (Baylor).

Fuchs et al. disclose a pourable, artificial nutritional composition having at least 1 kcal/ml and a viscosity below 100 mPa (see col. 7, lines 10-12 and 32-36). The temperature for this viscosity is not indicated, but the reference does not indicate that the composition is heated or cooled at this stage, and Applicants' 21° C is about room temperature. Thus, if the viscosity is about 7-40 mPa without heating or cooling, the viscosity is below 100 mPa at 21° C.

The composition contains, on a calorie basis, about 8-20% protein, 18-40% lipid and 40-65% carbohydrate (see col. 5, line 35, to col. 6, line 18). One example of the ratio of these components on a weight basis is, as protein:lipid:carbohydrate, 4.8:2.8:13, with a water content of about 79% (see col. 9, Example 1). The protein may be non-hydrolyzed whey protein (see col. 3, lines 7-10). These amounts fall within the numerical ranges of claims 31, 33 and 34. The composition also contains about 15-30% polyunsaturated fatty acids, with omega-6 and omega-3 fatty acids in a ratio of about 1:1 to 10:1 (see col. 5, lines 56-65). The carbohydrate may be

Art Unit: 1652

sucrose or fructose or other sugars, which have a glycemic index below 80 (see col. 6, lines 15-18; see also Zehner et al., col. 2, lines 28-37).

Fuchs et al. do not disclose that their composition contains lactoferrin or beta-lactoglobulin, a lactoferrin:beta-lactoglobulin ratio of greater than 1:15, or a lactoferrin:protein ratio greater than 35:1000 (greater than 0.035:1) by weight. Fuchs et al. also do not disclose the length of the fatty acid chains in their compositions or adding carnitine to their compositions.

Sainte-Radegonde discloses a pourable, artificial nutritional composition as a milk substitute in which a protein mixture is used to replace casein, the primary protein in milk. This protein mixture is easier to digest and is more well absorbed than the protein mixture naturally present in milk, and it has several other advantages. It restores health to those suffering from malnutrition or poor absorption from the GI tract. It provides a low-protein diet that is necessary for certain metabolic illnesses. It allows for recolonization of "Bifidus" type bacteria in the GI tract. It treats certain infections, particularly those causing diarrhea. It allows for the administration of iron in the form of an organic salt. It treats certain metabolic disorders, such as those caused by consuming milk with too little iron (see p. 2). This protein mixture contains 2% lactoferrin, within a range of 1.6 – 2.6%, and 47% beta-lactoglobulin, within a range of 32.9 – 61.1% (see p. 3, second paragraph). A ratio of 2.6% lactoferrin to 32.9% beta-lactoglobulin is 0.079, which exceeds a 1:15 ratio (0.067). It would have been obvious to one of ordinary skill in the art at the time that the invention was made to replace the protein component of Fuchs et al. with the protein mixture of Sainte-Radegonde, because Sainte-Radegonde discloses multiple health benefits derived from consuming this protein mixture, as discussed above- good digestion and absorption, good iron content, protection against infection and diarrhea, recolonization of beneficial normal flora, etc.

Regarding claim 37, as noted above, Sainte-Radegonde discloses that it is beneficial to use fatty acids that are of short and medium length, up to 20 carbons. Thus, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to use fatty acids containing 20 carbons or less in the compositions of Fuchs et al. Fuchs et al. disclose using medium chain monounsaturated and saturated fatty acids in the lipid component and that a source for the lipid component is a plant oil containing a mixture of unsaturated and saturated fatty acids, such as sunflower oil, safflower oil, rapeseed oil, olive oil or canola oil (see col. 5, line 48, to col. 6, line 8). Thus, one of ordinary skill in the art at the time that the invention was made would have reasonably expected the lipid component to have at least 5% by weight of short and medium chain fatty acids.

Regarding claim 39, Cavazza discloses milk compositions that are nutritional supplements and that contain 0.5-1.5 mg/ml of carnitine (see Table in col. 6). A carnitine concentration of 1 mg/ml is 0.1%. Cavazza discloses that carnitine (L-carnitine) is necessary for the beta-oxidation of fatty acids and the synthesis of essential polyunsaturated fatty acids (omega-3 and omega-6) from the fatty acids consumed in food (see col. 2, lines 52-62; col. 3, lines 33-49; and col. 4, line 25, to col. 5, line 15). It would have been obvious to one of ordinary skill in the art at the time that the invention was made to add at least 0.015% by weight of carnitine to one of the milk compositions of Fuchs et al., because Cavazza discloses that about 0.1% carnitine promotes the synthesis of therapeutic polyunsaturated fatty acids from the fatty acids normally present in milk and other comestible dairy products.

Regarding claim 40, Fuchs et al. disclose that their compositions are nutritional supplements intended for elderly patients with limited appetite, anorexic patients and patients with various digestive disorders (see col. 1, lines 10-21). An eight oz. serving, a reasonable size to consume for one with limited appetite, is about 237 ml. It would have been obvious to

Art Unit: 1652

one of ordinary skill in the art at the time that the invention was made to package single servings of these compositions for patient convenience, a practice in the area of nutritional supplements that was conventional at the time of the invention. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to package one of the compositions of Fuchs et al. in sizes of 20-400 ml.

Regarding claim 42, neither Fuchs et al. nor Sainte-Radegonde discloses a lactoferrin:protein ratio of greater than 0.035:1 (35:1000). Baylor discloses that the concentration of lactoferrin in human milk is about 1-3 g/L and that the functions of lactoferrin are to bind iron in milk in a form that is well absorbed through the GI tract and to inhibit bacterial infections (see p. 8, lines 30-37). Thus, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to add lactoferrin to a synthetic milk nutritional supplement, such as one of those of Fuchs et al., in the amount of 3 g/L. One milk composition of Fuchs et al. contains 4.8% protein by weight, or 48 g/L (see Example 1, col. 9). 3 g of lactoferrin to 48 g of protein is a ratio of 0.0625:1. The nutritional supplement milk compositions of Baylor contain less protein, 15-22 g/L of protein, which provides an even higher ratio of lactoferrin:protein. Therefore, this feature does not distinguish the claimed invention over the prior art.

Regarding claim 43, Lands discloses that omega-3 fatty acids are 20 carbons in length (see p. 2531, right col.). As discussed above, Fuchs et al. disclose that the lipid component in their compositions has 15-30% polyunsaturated fatty acids (omega-3 and omega-6). Thus, one of ordinary skill in the art at the time that the invention was made would have reasonably expected the lipid component in the compositions of Fuchs et al. to have at least 5% by weight of omega-3 fatty acids that are 20-22 carbons in length.

Art Unit: 1652

Regarding claim 44, this claim reads on a composition having no glycomacropeptide. Fuchs et al. and Sainte-Radegonde do not disclose that their compositions contain glycomacropeptide. Thus, this claim limitation does not distinguish Applicants' invention over the prior art.

In short, the claimed invention reads on a synthetic milk composition of Fuchs et al. in which the protein component is substituted with the protein mixture of Sainte-Radegonde (the multiple health benefits of which are disclosed by Sainte-Radegonde) and in which the lactoferrin concentration has been increased to a physiological concentration. The beneficial effects of lactoferrin are disclosed by Sainte-Radegonde and Baylor (cited in Applicants' IDS), as well as by most of the other references cited in Applicants' IDS (e.g., Troost et al.; Kakunai Juyotai Kenkyusho KK, JP 2003-137808; Kruzel et al., WO 98/50076; Spilburg et al., WO 01/8955; and Pola et al., WO 02/40013).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2007-08-01

Rosanne Kosson

Rebecca E. Gentry
REBECCA E. GENTRY
PRIMARY EXAMINER
GROUP 1652
1652